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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0502; FRL-11272-01-OCSPP]

Trifluralin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trifluralin in or on tea, dried and tea, instant. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Objections and requests for hearings must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0502, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2022-0502 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [**INSERT DATE**

60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0502, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2022 (87 FR 43231) (FRL-9410-03-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8999) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR 180.207 be amended by establishing a tolerance for residues of the herbicide trifluralin in or on tea at 0.05 parts

per million (ppm). That document referenced a summary of the petition prepared by Gowan Company, which is available in the docket at *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances for tea, dried and tea, instant. For details, see Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for trifluralin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trifluralin follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance

rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for trifluralin in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to trifluralin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the toxicological profile of trifluralin, see Unit III.A. of the trifluralin tolerance rulemaking published in the **Federal Register** of February 15, 2019 (84 FR 4345) (FRL-9983-89).

Toxicological points of departure/levels of concern. A summary of the toxicological endpoints for trifluralin used for human health risk assessment is discussed in Unit III.B. of the trifluralin tolerance rulemaking published in the **Federal Register** of July 31, 2013 (78 FR 46267) (FRL-9393-5). EPA notes that the unit of measurement for the no-observed-adverse-effect level (NOAEL) in the inhalation short-term (1 to 30 days) exposure/scenario should be mg/m^3, not mg/kg/day as presented (i.e., the inhalation study NOAEL = 300 mg/m^3). The unit of measurement for the lowest-observed-adverse-effect level (LOAEL) is correct as presented (i.e., LOAEL = 1000 mg/m^3).

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the requested tolerance for residues of trifluralin on tea and were conducted with the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM-FCID, ver. 4.02), which incorporates food consumption data from the United States Department of Agriculture (USDA) National

Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2005-2010). The unrefined acute dietary exposure and risk assessment assumed 100 percent crop treated (PCT) for all commodities. The partially refined chronic and cancer dietary exposure and risk assessments incorporated average PCT estimates. As to residue levels in food, the chronic and cancer exposure assessments incorporated tolerance-level residues for the majority of commodities, average screening level usage analysis (SLUA) PCT estimates, EPA's default processing factors, and monitoring data from the USDA's Pesticide Data Program (PDP) for a subset of risk driving commodities that significantly reduced the cancer dietary exposure estimates. Dietary exposure estimates for the established uses and requested tolerance are below EPA's level of concern for the general population and all population subgroups.

Anticipated residue and PCT information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require, pursuant to FFDCA section 408(f)(1), that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the chronic dietary assessment, the following PCT assumptions were made: asparagus 15%; barley 1%; beans, green 25%; broccoli 10%; cabbage 35%; canola 2.5%; cantaloupes 25%; carrots 15%; cauliflower 5%; celery 2.5%; corn 1%; cotton 25%; cucumbers 5%; dry beans/peas 10%; honeydews 30%; onions 1%; peaches 1%; peanuts 2.5%; peas, green 10%; pecans 1%; peppers 20%; potatoes 2.5%; pumpkins 2.5%; sorghum 1%; soybeans 2.5%; squash 2.5%; sugar beets 1%; sunflowers 5%; tomatoes 50%; and watermelons 15%. EPA assumed 100 PCT for the other commodities including tea. In the acute analysis, the Agency made the conservative assumption of 100 PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use 1% or 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest

observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in this section have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations are taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimates do not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which trifluralin may be applied in a particular area.

Drinking water and non-occupational exposures. Because there are no registrations for use of trifluralin on tea in the United States associated with the requested tolerance, the estimated drinking water concentrations and residential exposure assessment have not changed. For a detailed summary of the drinking water analysis and residential exposure assessment for trifluralin used for the human health risk assessment, see Unit III.B. and C. of the February 15, 2019, trifluralin tolerance rulemaking.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider

"available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Based on a review of the toxicological database for trifluralin and the other dinitroanilines (benfluralin, butralin, ethalfluralin, fluazinam, flumetralin, oryzalin, pendimethalin, and prodiamine), the Agency has determined that although trifluralin shares some chemical and/or toxicological characteristics (e.g., chemical structure or apical endpoint) with these other dinitroanilines, the toxicological database does not support a testable hypothesis for a common mechanism of action. No further data are required to determine that no common mechanism of toxicity exists for trifluralin and the other dinitroanilines and no further cumulative evaluation is necessary for trifluralin. For additional details, refer to the document titled "Dinitroanilines: Screening Analysis of Toxicological Profiles to Consider Whether a Candidate Common Mechanism Group Can Be Established" in docket ID number EPA-HQ-OPP-2017-0420 at *https://www.regulations.gov*.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.B. of the February 15, 2019, trifluralin tolerance rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and Determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departures to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the aPAD; they are <1% of the aPAD for females 13 to 49 years old,

the only population group of concern. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD; they are 5.6 % of the cPAD for all infants <1 year old, the population group receiving the greatest exposure. EPA's short-term aggregate exposure to trifluralin is based on residential and dietary routes of exposure. The short-term aggregate MOEs are 24,000 for adults and 15,000 for children 1 to less than 2 years old and are not of concern (i.e., the MOEs are > the LOC of 100). Trifluralin is not registered for any use patterns that would result in intermediate-term residential exposure, so intermediate-term aggregate risk is the same as the chronic dietary risk and is not of concern.

A cancer aggregate assessment was conducted for trifluralin since it is classified as a "Group C, Possible Human Carcinogen" with a Q_1* of 2.96 x10^{-3} $(mg/kg/day)^{-1}$ based upon male rat thyroid follicular cell combined adenoma, papillary adenoma, cystadenoma, and carcinoma tumor rate in human equivalents. The cancer aggregate risk assessment combines food and drinking water exposures with the residential dermal and inhalation exposure from post-application exposure from treated gardens. The resulting aggregate cancer risk estimate is 1.5×10^{-6}.

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. EPA has concluded

the cancer risk for all existing trifluralin uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus not of concern.

Therefore, based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to trifluralin residues. More detailed information on this action can be found in the document titled "Trifluralin. Human Health Risk Assessment for a Section 3 Tolerance without U.S. Registration on Imported Tea" in docket ID EPA-HQ-OPP-2022-0502.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods, Methods GRM 96.12 and GRM 96.13 for plant commodities, are available for trifluralin and utilize gas chromatography (GC) with electron capture detection (ECD). The reported limit of quantitation (LOQ) is 0.01 ppm.

Trifluralin was evaluated using the Food and Drug Administration (FDA) multiresidue method, which is also suitable for enforcement in determining residues of trifluralin in plant commodities.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex has not established MRLs for trifluralin on tea commodities.

C. *Revisions to Petitioned-For Tolerance*

The petition requested a tolerance for residues of trifluralin in or on tea at 0.05 ppm. Because residue data was provided for a processed tea commodity rather than the

raw agricultural commodity (i.e., tea, plucked leaves), EPA is establishing tolerances at 0.05 ppm on all of the processed tea commodities (i.e., tea, dried and tea, instant).

V. Conclusion

Therefore, tolerances are established for residues of trifluralin, 2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)benzenamine, in or on tea, dried and tea, instant at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of

FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 14, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.207, amend paragraph (a) by designating the table as table 1 and adding in alphabetical order in newly designated table 1 to paragraph (a) the entries "Tea, dried[1]" and "Tea, instant[1]" and footnote 1 following the table to read as follows:

§ 180.207 Trifluralin; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Tea, dried[1]	0.05
Tea, instant[1]	0.05
* * * * * * *	

[1] There are no U.S. registrations as of [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

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[FR Doc. 2023-18180 Filed: 8/23/2023 8:45 am; Publication Date: 8/24/2023]